

Notice of Allowability	Application No.	Applicant(s)	
	09/833,637	KODAMA ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/10/04.
2. ☒ The allowed claim(s) is/are 22,23 and 25-38.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 10/22/01.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>0704</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Dadio on July 21, 2004.

Examiner's Amendments to the claims:

Cancel claim 24.

Claims 23, 26, 27, 29, 32 and 35-38 have been amended as follows:

Claim 23 (Currently amended) A pharmaceutical composition for treating a gastrointestinal disease caused by *Helicobacter pylori* in mammals, comprising the inhibitor composition according to Claim 22 and a pharmaceutically acceptable carrier.

Claim 26 (Currently amended) A pharmaceutical composition for treating a gastrointestinal disease caused by *Helicobacter pylori* in mammals, comprising the inhibitor according to Claim 22, [and] an inhibitor of gastric acid secretion and a pharmaceutically acceptable carrier.

Claim 27 (Currently amended) A process for preparing a glycoprotein which specifically binds to urease of *Helicobacter pylori*, comprising contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

Claim 29 (Currently amended) A process for preparing a glycoprotein as an inhibitor of *Helicobacter pylori* colonization, comprising contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

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Claim 32 (Currently amended) The inhibitor composition according to Claim [22] 31, wherein the urease immobilized on the column is [recombinant urease] recombinantly produced.

Claim 35 (Currently amended). A method for inhibiting *Helicobacter pylori* colonization in mammals [including humans], comprising orally administering to [a] said mammal a glycoprotein which specifically binds to urease of *Helicobacter pylori* in an effective amount for inhibiting *Helicobacter pylori* colonization, wherein the glycoprotein [being] is obtained by [isolation and purification from] contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs [using a method which utilizes specific adsorption to *Helicobacter pylori*] with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

Claim 36 (Currently amended). A method for inhibiting *Helicobacter pylori* colonization in mammals [including humans], comprising orally administering to [a] said mammal a glycoprotein which specifically binds to urease of *Helicobacter pylori* and an inhibitor of gastric acid secretion in an effective amount for inhibiting *Helicobacter pylori* colonization, wherein the glycoprotein [being] is obtained by [isolation and purification from] contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs [using a method which utilizes specific adsorption to *Helicobacter pylori* urease] with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

Claim 37 (Currently amended) A method for treating a gastrointestinal disease caused by *Helicobacter pylori* in mammals [including humans], comprising orally administering to [a] said mammal a glycoprotein which specifically binds to urease of *Helicobacter pylori* in an effective amount for treating the disease [so as to inhibit] by inhibiting *Helicobacter pylori* colonization, wherein the glycoprotein [being] is obtained by [isolation and purification from] contacting a glycoprotein-containing substance from

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whey of bovine milk or albumen of chicken eggs [using a method which utilizes specific adsorption to *Helicobacter pylori* urease] with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

Claim 38 (Currently amended) A method for treating a gastrointestinal disease caused by *Helicobacter pylori* in mammals [including humans], comprising orally administering to [a] said mammal a glycoprotein which specifically binds to urease of *Helicobacter pylori* [in] and an inhibitor of gastric acid secretion in an effective amount for treating the disease [so as to inhibit] by inhibiting *Helicobacter pylori* colonization, wherein the glycoprotein [being] is obtained by [isolation and purification from] contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs [using a method which utilizes specific adsorption to *Helicobacter pylori* urease] with *Helicobacter pylori* urease and isolating and purifying the glycoprotein specifically bound to the urease.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be the closest art to the claimed invention. Peterson et al. (U. S. Patent 5,505,955) teach a glycoprotein, which has a molecular weight of 46 kDa and is isolated upon fractionation of human milk fat globules; and Hirno et al. (FEMS Immunology and Medical Microbiology 20, 275-281 (1998)) teach a mucin derived from fat globule membrane, which inhibits the adherence of urease to gastric mucin weakly. Furthermore, the references do not teach a glycoprotein isolated from high molecular weight whey concentrate (>1000 kDa) or high molecular weight albumen protein concentrate (>300 kDa) and purified by affinity chromatography using its specific adsorption to *Helicobacter pylori* urease. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
July 21, 2004

Jon P. Weber
Supervising
Jon P. Weber, Ph.D.
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